



Food and Drug Administration
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September 18, 2015

Propel Orthodontics, LLC
c/o Mr. Craig J. Coombs
Coombs Medical Device Consulting, Inc.
1193 Sherman Street
Alameda, California 94501

Re: K150392

Trade/Device Name: PROPEL Device
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZJ
Dated: August 18, 2015
Received: August 19, 2015

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang
-S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150392

Device Name

PROPEL Device

Indications for Use (Describe)

The PROPEL device is indicated for manually drilling holes in tissue and bone for orthodontic and dental operative procedures including initiation holes for drill bits, implants, screws, plates and other orthodontic appliances.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary**A. Device Information:**

Category	Comments
Sponsor:	Propel Orthodontics, LLC. 384 South Abbott Avenue Milpitas, CA 95035 Company Contact: Bryce Way Chief Executive Officer Tel: 408-394-5851 Email: BW@PropelOrtho.com
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Manual Bone Drill
Device Classification Number & Name:	21 CFR 872.4120 Bone Cutting Instrument and Accessories
Device Classification & Product Code:	Class II, DZJ
Device Proprietary Name:	PROPEL Device

Predicate Device Information:

Predicate Device:	90° Screwdriver
Predicate Device Manufacturer:	Synthes
Predicate Device Common Name:	Manual Screwdriver & Bone Drill
Predicate Device Premarket Notification #	K082649
Predicate Device Classification & Name:	21 CFR 872.4120 Bone Cutting Instrument and Accessories
Predicate Device Classification & Product Code:	Class II, DZJ

B. Date Summary Prepared

14 September 2015

C. Description of Device

The PROPEL Device is intended for use in dental operative procedures involving the preparation of tissue and bone. The PROPEL Device can be used manually as a bone cutting instrument in accordance with the FDA regulation 21 CFR Sec. 872.4120. It CANNOT be attached to any powered driver.

The PROPEL Device has a stainless steel drill tip that can be manually adjusted to the length needed for treatment or cutting depth. The plastic handle incorporates a retractable plastic tube

over the cutting drill instrument. This enables the drill tip to be locked into a specific depth at 3, 5, or 7mm, thus preventing the drill tip from penetrating the bone beyond the targeted depth when used during orthodontic and dental operative procedures. The handle contains a red LED, operated by batteries. The LED is illuminated when the tip of the drill tip reaches the set depth. There is no motor in the device. The batteries are only for signaling when the prescribed depth has been achieved.

The device is provided sterile and is for single use only.

D. Indications for Use

The PROPEL device is indicated for manually drilling holes in tissue and bone for orthodontic and dental operative procedures including initiation holes for drill bits, implants, screws, plates and other orthodontic appliances.

E. Comparison to Predicate Device

The PROPEL device is substantially equivalent in intended use, technology, design, materials, and physician use as that found in the predicate Synthes 90° Screwdriver (K082649).

Product Code Equivalence

Both the subject PROPEL device and the predicate Synthes 90° Screwdriver have identical product codes: DZJ.

Indications for Use Equivalence

The subject device is indicated “for manually drilling holes in tissue and bone for orthodontic and dental operative procedures including initiation holes for drill bits, implants, screws, plates and other orthodontic appliances.”

The predicate device is indicated “for the manual and powered pre-drilling and insertion of bone fixation screws in oral/maxillofacial surgery.”

Both devices are bone-cutting devices for initiation holes for screws and other devices. The PROPEL device is a manual drill, whereas the predicate device is a powered drill. The subject device does not have a screwdriver function like the predicate. As a result, the subject device is indicated for a subset of performance features of the predicate device.

Because subject device features are a subset of the predicates, they do not raise new questions of safety or efficacy; they allow the conclusion of substantial equivalence between the Indications for Use.

Technological Equivalence

Both devices use rotating steel drill bits to cut holes in the bone of the upper or lower jaw. They differ in that the predicate device is a pneumatically powered drill, and the subject device is a manually powered drill.

Comparison of Technological Aspects of the Predicate and Application Devices

Characteristic	Predicate Device: Synthes 90° Screwdriver K082649	Subject Device: Propel Orthodontics, LLC PROPEL Device	How do differences, if any, pertain to justification of substantial equivalence?
Operating Principle	Hand-held powered drill or hand-held manual screwdriver	Hand-held manual drill	Difference in power mode and lack of screwdriver function in application device does not raise new questions of safety or efficacy.
Drill Angle	Drills holes or inserts screws at a 90° angle from the handle	Drills holes at a 0° angle (i.e. inline) with the handle	Difference in angle does not raise new questions of safety or efficacy for what the application device is indicated for
Powered or Manual	Screwdriver intended to operate manually; Drill intended to operate connected to a mechanical power source compatible with a Intra coupling according to ISO 3964/EN 23 964	Manually operated drill	Difference in power mode and lack of screwdriver function in application device does not raise new questions of safety or efficacy.
Direct drive or geared?	2:1 gearing ratio when turning proximal end	No gearing, device is turned by rotating proximal end	No clinical difference
Method for creating holes	Stainless Steel Drill Bit	Stainless Steel Drill Bit	Clinically Identical
Interchangeable drill bits	Yes	No. Drill bit built-in	Identical result as far as creating holes

Characteristic	Predicate: Synthes 90° Screwdriver (K082649)	Subject Device: Propel Orthodontics, LLC PROPEL Device	How do differences, if any, pertain to justification of substantial equivalence?
Drill Bit OD	1.0 – 2.4mm	1.6mm	Size available in application device is a subset of those available in the predicate device
Drill Bit Working Length	4 – 18mm	3, 5, or 7 mm	The smaller length available in the application device are to serve the techniques described in the Indication for Use. Does not raise new questions of safety or efficacy
Depth Stops	Yes, by selecting the appropriate length bit	Yes, by adjusting the depth stop on the drill.	Clinically Identical
Types of Screwdriver bits	Screwholder bits for screw OD's of 1.5, 2.0 and 2.4mm	None. Device cannot be converted into a screwdriver	Raises no questions of safety or efficacy
Indicator of Achievement of Proper Depth	Head of drill in contact with tissue	LED light comes on to prevent unwarranted pressure on tissue	Clinically Identical
Materials: Drill Bits	Stainless Steel	Stainless Steel	Clinically Identical
Materials: device body	Metallic	ABS and polycarbonate	Clinically Identical
Single Use?	Reusable	Single Use Only	Clinically Identical
Sterilization	Provided non-sterile, can be resterilized	Provided sterile	Clinically Identical after sterilization of predicate

Design Equivalence:

The subject and predicate devices use steel drill bits to cut holes in the bone of upper or lower jaw. The diameter of the holes created by the PROPEL device are a subset of those available from the predicate device. Both devices allow the user to control the depth of the hole. The predicate uses different length bits to achieve the intended depth. The subject device has a retractable sleeve around its drill bit that allows the physician to preselect the hole depth up to 7mm. The predicate device drills holes at a 90° angle to the axis of the handle, whereas the subject device drills holes in-line with the axis of the handle.

Propel Orthodontics, LLC, concludes that the subject PROPEL device and the predicate Synthes 90° Screwdriver are substantially equivalent.

F. Summary of Supporting Data

Biocompatibility data demonstrates that the PROPEL device is in compliance with ISO 10993-1: *Biological evaluation of medical devices* as described in ISO 7405: *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*.

Sterilization validation according to ISO 11137-1, -2, and -3 to ensure a SAL of 10^{-6} and shelf-life validation according to ASTM F1980-07 were conducted to validate the 2 year shelf-life of the PROPEL device.

Electrical safety testing demonstrates that the PROPEL device is in compliance with IEC 60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* and IEC 60601-1-2: *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*.

Bench testing has demonstrated that the PROPEL is in compliance with its product specifications, the expectations of the medical community and the product labeling. The following bench tests were conducted to demonstrate the Propel device's performance.

- Bit reliability, including deflection resistance and hole depth repeatability
- Various tensile and compression tests of components
- Dial and bit depth reliability
- LED light reliability

A clinical literature article¹ has documented that the PROPEL device can create holes through the gum tissue into alveolar bone in humans.

G. 510(k) Summary Conclusion

In accordance with 21CFR807.92(b)(3), it can be concluded from the nonclinical testing and the clinical literature that the PROPEL device is as safe and as effective as the predicate device in the context of its Indications for Use and technological characteristics.

It can be concluded that the PROPEL device is substantially equivalent to the predicate Synthes 90° Screwdriver.

¹ Alikhani M, Raptis M, Soldan B, *et al.* Effect of micro-osteoperforations on the rate of tooth movement. Am J Orthod Dentofacial Orthop. 144:639-48; 2013.